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EPA SANITIZED

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-13-0930
	)	
	)	
	)	
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	)	

Consent Order and Determinations Supporting Consent Order

[redacted]

EPA SANITIZED

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[redacted]

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-13-0930 for the chemical substance [redacted] ("the PMN substance") submitted by [redacted] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

(a) submit to EPA certain toxicity testing before manufacturing (defined by statute to include import) a total of [redacted], whichever occurs later;

(b) submit to EPA certain toxicity testing before manufacturing (defined by statute to include import) a total of [redacted], whichever occurs later;

(c) provide personal protective equipment to its workers to prevent dermal exposure;

(d) provide respirators to its workers to prevent inhalation exposure;

(e) label containers of the PMN substance and provide Material Safety Data Sheets ("MSDSs") and worker training in accordance with the provisions of the Hazard Communication Program section;

(f) not use the PMN substance other than as an intermediate;

(g) distribute the PMN substance only to a person who agrees to follow the same restrictions (except the testing requirements) and to not further distribute the PMN substance until it has been completely reacted (cured) or incorporated into a polymer matrix;

(h) provide the U.S. EPA with a 1 gram sample of the PMN materials upon request by EPA;

(i) comply with the Release to Water provisions; and,

(j) maintain certain records.

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Chemical Identity:

Specific: [redacted]

Generic: Substituted phenol

Use:

Specific: [redacted]

Generic: Reactant in polymerization reaction

Maximum 12-Month Production Volume: [redacted] kilograms

Test Data Submitted with PMN:

Human estrogen recombinant yeast assay
Human androgen recombinant yeast assay
U2OS cell ERα redistribution reporter assay
U2OS cell AR redistribution reporter assay
96-hour *Pimephales promelas* (fathead minnow)
48-hour *Daphnia magna*
96-hour *Pseudokirchneriella subcapitata*
Ready Biodegradability OECD 301b

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects Summary:

Absorption: Absorption is nil through the skin for the neat material, poor through the skin for the material in solution, and poor through the lung and GI tract based on physical/chemical properties.

Toxicological Endpoints of Concern: There are concerns for liver, kidney and developmental toxicity, blood effects, sensitization, and endocrine disruption.

Basis: [redacted]

Environmental Effects Summary:

Chronic fish and daphnid studies on the PMN substance indicate a concentration of concern (COC) of 6 parts per billion.

Exposure and Environmental Release Summary:

Manufacturing of the PMN substance is expected to occur by the Contract Manufacturer, [redacted].

	Manufacture	Use
# Sites	[redacted]	[redacted]
Workers (#/site)	[redacted]	[redacted]
Exposure (days/year)	[redacted]	[redacted]
Dermal Exposure (mg/day)	[redacted]	[redacted]

Inhalation Exposure (mg/day)	[redacted]	[redacted]
Releases (days/year)	[redacted]	[redacted]
Release to Water (kg/day)	[redacted]	[redacted]
Surface Water Concentration (ppb)	[redacted]	[redacted]
Days Exceeding Concern Level	[redacted]	[redacted]

Risk to Workers:

The available toxicity data for [redacted] indicates that its most sensitive toxicity endpoint is developmental toxicity. Based on the point of departure (LOAEL = 50 mg/kg/day) for this endpoint, there are human health risk for workers in the two occupational scenarios (manufacturing and use). Estimated risks in the form of MOE using the LOAEL of 50 mg/kg/day for developmental toxicity and an acceptable MOE of 1000 to account for intraspecies and interspecies variations and LOAEL to NOAEL extrapolation are presented in table below:

Route of Exposure	Per Day Dose* (mg/day)		Absorption Factor*		Avg. Adult BW (kg)		PMN Dose (mg/kg-d)	divided into	LOAEL (mg/kg-d)		Margin of Exposure (MOE) (Acceptable MOE ≥1000)
Occupational Scenario: PMN Manufacturing											
Inhalation	[redacted]	x	1.5	/	80	=	[redacted]	into->	50	=	[redacted]
Dermal	[redacted]	x	1.5	/	80	=	[redacted]	into->	50	=	[redacted]
Occupational Scenario: USE - Reactant in Polymer Synthesis											
Inhalation	[redacted]	x	1.5	/	80	=	[redacted]	into->	50	=	[redacted]
Dermal	[redacted]	x	1.5	/	80	=	[redacted]	into->	50	=	[redacted]

* The absorption factors for the dermal and inhalation routes of exposure have been estimated to be 150% of the oral absorption. This assumption is based on reports indicating that [redacted] is metabolized to its biologically inactive form, [redacted].

in adult rats more quickly after oral administration due to first pass elimination. Therefore, non oral [redacted] doses are expected to have a greater biological effect than the same doses delivered by the oral route in adult laboratory animals.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health effects from exposure to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

(b) In light of the potential risk of human health effects posed by the uncontrolled manufacture (defined by statute to include import), processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture (defined by statute to include import), processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance [redacted] (P-13-930)("the PMN substance") in the United States by [redacted] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company

involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured) or incorporated into a

polymer matrix.

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE (INCLUDING IMPORT), PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing (defined by statute to include import), processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the

appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at *www.epa.gov/oppt/tsca8e*.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

Room 7117B

1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing (defined by statute to include import) the PMN substance after a certain aggregate domestic manufacture volume ("the production limit"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Test Guideline
Tier 1		
[redacted]	Aromatase (Human Recombinant)	OCSPP 890.1200
	Steroidogenesis (Human Cell Line – H295R)	OCSPP 890.1550 or OECD 456
Tier 2		
[redacted]	90-Day Oral Toxicity	OPPTS 870.3100 or OECD 408
	Amphibian Metamorphosis	OCSPP 890.1100 or OECD 231
	Fish Short-Term Reproduction	OECD 229 or OCSPP 890.1350
	Hershberger (Rat)	OECD 441 or OCSPP 890.1400
	Female Pubertal (Rat)	OCSPP 890.1450
	Male Pubertal (Rat)	OCSPP 890.1500
	Uterotrophic (Rat)	OECD 440 or OCSPP 890.1600

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be

submitted after reaching the applicable production limit). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit

the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture (defined by statute to include import) beyond the applicable production limit.

(j) Unreasonable Risk.

EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture (defined by statute to include import), processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture (defined by statute to include import), process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of

receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(4) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and

Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results shall be reported as the cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to

the PMN substance alone and in likely combination with other chemical substances in the work area.

(3) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(4) of this section is provided with and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an Applied Protection Factor ("APF") of 50, from the respirators listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.

(4) Physical States. The following physical state of airborne chemical substances is listed for subparagraphs (a)(1) and (3) of this section: Particulate (including solids or liquid droplets).

(5) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(3) of this section:

(i) Any NIOSH-certified **air-purifying** full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s).

(ii) Any NIOSH-certified **powered air-purifying** respirator equipped with a tight-fitting facepiece (half or full facepiece) and equipped with HEPA filters.

(iii) Any NIOSH-certified pressure-demand or other positive pressure mode **supplied-air** respirator equipped with a half-mask.

(iv) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece.

(v) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a tight-fitting facepiece (half or full facepiece).

(vi) Any NIOSH-certified negative pressure (demand) **self-contained breathing apparatus** (SCBA) equipped with a hood or helmet or a full facepiece.

(b) De Minimis Concentrations. The requirements of this section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the

substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling.

(1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted

by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) De Minimis Concentrations. The requirements of this Hazard Communication section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains (1) New Chemical Exposure Limits provisions that specify a NCEL concentration less than the de

minimis concentration specified here, or (2) Release to Water provisions that prohibit release to water or specify in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) sensitization.

(ii) internal organ effects.

(ii) developmental effects.

(iv) eye irritation

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) avoid ingestion.

(iv) use respiratory protection.

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(5) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

(g) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture (defined by statute to include import) of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final rule modifying the significant new use rule ("SNUR") at 40 CFR 721.5740 to be consistent with the conditions set forth in this order, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the modified SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final modified SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture (defined by statute to include import) the PMN substance of the existence of the SNUR.

(4) Subparagraph (a)(2) shall not negate the effects of any fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2).

(b) Contract Manufacturer. Not withstanding paragraph (a), the Company may cause the Contract Manufacturer(s) identified in the PMN and listed in the Preamble of this Order to manufacture (defined by statute to include import) the PMN substance according to the following conditions (the Company may petition EPA pursuant to Section VI of this Order to include additional Contract Manufacturers):

(1) The Contact Manufacturer must be under contract to the Company to manufacture (defined by statute to include import) the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for the Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture (defined by statute to include import).

(3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with the conditions specified in the Consent Order for Contract Manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance only upon written notification from the Agency.

USE

(a) The Company shall not use the PMN substance other than as an intermediate.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN

number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. Except after the PMN has been completely reacted (cured), incorporated into a polymer matrix, or as provided in paragraph (c), the Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or incorporated into a polymer matrix. A Contract Manufacturer identified in a fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2) of the Manufacturing section of this Order may further distribute the PMN substance(s) to the Company.

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace section of this Order.

(4) Comply with the same requirements and restrictions, if any, required of the Company in the Hazard Communication Program section of this Order.

(5) Comply with the same environmental release restrictions, if any, required of the

Release to Water section of this Order.

(6) Not use the PMN substance other than as an intermediate.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Subparagraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final rule modifying the SNUR at 40 CFR 721.5740 to be consistent with the conditions set forth in this order, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (b)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of

the SNUR affirmed.

(2) When EPA promulgates a final modified SNUR for the PMN substance and subparagraph (b)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (b).

RELEASE TO WATER

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Company is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing/processing/use containing the PMN substance into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds 6 parts per billion, when calculated using the methods described in 40 CFR 721.91. However, 40 CFR 721.91(a)(4) does not apply. Instead, if control technologies are in place to treat the waste stream containing the PMN substance, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 40 percent removal efficiency may be attributed to such treatment.

In lieu of calculating the quotient, monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (defined by statute to include import) volume of the PMN substance and the corresponding dates of manufacture (defined by statute to include import);

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (defined by statute to include import) to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (defined by statute to include import), processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(7) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(8) Copies of labels required under the Hazard Communication Program section of this Order;

(9) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(10) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(11) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(12) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(13) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured (defined by statute to include import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture (defined by statute to include import) of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in

Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to:

The written notice should be submitted to EPA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Courier Delivery Address

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1201 Constitution Avenue, N.W.

Washington, D.C. 20004

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured (defined by statute to include import). Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured (defined by

statute to include import) by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

10/29/14
Date

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

[redacted]

[redacted]

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture (defined by statute to include import) the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured (defined by statute to include import) or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)

_____

Successor's Technical Contact

_____

Address

_____

City, State, Zip Code

_____

Phone

ATTACHMENT C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-13-0930
	)	
	)	
	)	
	)	
	)	

Consent Order for Contract Manufacturer

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. [redacted] ("the Contract Manufacturer") has entered into a contract with [redacted] ("the Company") to manufacture exclusively for the Company the chemical substance [redacted] (P-13-930)("the PMN substance"). The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in the United States by the Contract Manufacturer, except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Contract Manufacturer begins commercial manufacture of the PMN substance for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Contract Manufacturer begins to manufacture the PMN substance for use in the United States, no further activity by the Contract Manufacturer involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h),

with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted (cured) or incorporated into a polymer matrix.

(c) Automatic Sunset. If the Contract Manufacturer has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE (INCLUDING IMPORT), PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

As a condition of manufacturing (defined by statute to include import) the PMN substance for the Company, the Contract Manufacturer is prohibited from manufacturing (defined by statute to include import), processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects

of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

Triggered Testing Requirements. The Contract Manufacturer is prohibited from manufacturing (defined by statute to include import) the PMN substance after a certain aggregate domestic manufacture volume ("the production limit"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Test Guideline
Tier 1		
[redacted]	Aromatase (Human Recombinant)	OCSPP 890.1200
	Steroidogenesis (Human Cell Line – H295R)	OCSPP 890.1550 or OECD 456
Tier 2		
[redacted]	90-Day Oral Toxicity	OPPTS 870.3100 or OECD 408
	Amphibian Metamorphosis	OCSPP 890.1100 or OECD 231
	Fish Short-Term Reproduction	OECD 229 or OCSPP 890.1350
	Hershberger (Rat)	OECD 441 or OCSPP 890.1400

Female Pubertal (Rat)	OCSPP 890.1450
Male Pubertal (Rat)	OCSPP 890.1500
Uterotrophic (Rat)	OECD 440 or OCSPP 890.1600

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substance at any site controlled by the Contract Manufacturer (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substance), the Contract Manufacturer must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(4) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Demonstration of Imperviousness. The Contract Manufacturer is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious

barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results shall be reported as the cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(3) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(4) of this

section is provided with and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an Applied Protection Factor ("APF") of 50, from the respirators listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.

(4) Physical States. The following physical state of airborne chemical substances is listed for subparagraphs (a)(1) and (3) of this section: Particulate (including solids or liquid droplets),

(5) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(3) of this section:

(i) Any NIOSH-certified **air-purifying** full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s).

(ii) Any NIOSH-certified **powered air-purifying** respirator equipped with a tight-fitting facepiece (half or full facepiece) and equipped with HEPA filters.

(iii) Any NIOSH-certified pressure-demand or other positive pressure mode **supplied-air** respirator equipped with a half-mask.

(iv) Any NIOSH-certified negative pressure (demand) **supplied-air** respirator equipped with a full facepiece.

(v) Any NIOSH-certified continuous flow **supplied-air** respirator equipped with a tight-fitting facepiece (half or full facepiece).

(vi) Any NIOSH-certified negative pressure (demand) **self-contained breathing apparatus** (SCBA) equipped with a hood or helmet or a full facepiece.

(b) De Minimis Concentrations. The requirements of this section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Contract Manufacturer has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company or Contract Manufacturer becomes aware that the PMN substance may present a risk of injury to health or the environment (or is so notified by EPA), the Contract Manufacturer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Contract Manufacturer must ensure that persons who will receive the PMN substance from the Contract Manufacturer, or who have received the PMN substance from the Contract Manufacturer within 5 years from the date the Contract Manufacturer becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Contract Manufacturer becomes aware of the new information.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Contract Manufacturer shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Contract Manufacturer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Contract Manufacturer may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Contract Manufacturer or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS

for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Contract Manufacturer is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Contract Manufacturer will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Contract Manufacturer will use to inform contractors of the presence of the PMN substance in the Contract Manufacturer's workplace and of the provisions of this Order if employees of the contractor work in the Contract Manufacturer's workplace and are reasonably likely to be exposed to the PMN substance while in the Contract Manufacturer's workplace.

(b) Labeling.

(1) The Contract Manufacturer shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section or by the Contract Manufacturer, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Contract Manufacturer, for the PMN substance.

(ii) The Contract Manufacturer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Contract Manufacturer need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Contract Manufacturer shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Contract Manufacturer unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Contract Manufacturer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Contract Manufacturer, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Contract Manufacturer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Contract Manufacturer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Contract Manufacturer must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Contract Manufacturer

becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Contract Manufacturer must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Contract Manufacturer, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Contract Manufacturer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Contract Manufacturer.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Contract Manufacturer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Contract Manufacturer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Contract Manufacturer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Contract Manufacturer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Contract Manufacturer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Contract Manufacturer becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Contract Manufacturer becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Contract Manufacturer's workplace, the Contract Manufacturer must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Contract Manufacturer must ensure that persons receiving the PMN substance from the Contract Manufacturer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Contract Manufacturer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Contract Manufacturer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Contract Manufacturer must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted by the Contract Manufacturer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Contract Manufacturer has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release

required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Contract Manufacturer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) De Minimis Concentrations. The requirements of this Hazard Communication section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Contract Manufacturer has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains (1) New Chemical Exposure Limits provisions that specify a NCEL concentration less than the de minimis concentration specified here, or (2) Release to Water provisions that prohibit release to water or specify in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) sensitization.

(ii) internal organ effects.

(ii) developmental effects.

(iv) eye irritation.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) avoid ingestion.

(iv) use respiratory protection,

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(5) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

(g) Existing Hazard Communication Program. The Contract Manufacturer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

MANUFACTURING

(a)(1) Prohibition. The Contract Manufacturer shall not begin manufacture (defined by statute to include import) of the PMN substance until the Contract Manufacturer or the Company receives a fully executed copy of the Consent Order for Contract Manufacturer from EPA.

(2) The Contract Manufacturer shall not cause, encourage, or suggest the manufacture (defined by statute to include import) of the PMN substance by any other person.

(3) Sunset Following SNUR. Subparagraph (a)(2) shall expire 75 days after promulgation of a final rule modifying the significant new use rule ("SNUR") at 40 CFR 721.5740 to be consistent with the conditions set forth in this order, unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the modified SNUR. If the Contract Manufacturer is so notified, subparagraph (a)(2) shall not expire until EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(4) Notice of SNUR. When EPA promulgates a final modified SNUR for the PMN substance and subparagraph (a)(2) expires in accordance with subparagraph (a)(3), the Contract Manufacturer shall notify each person whom it causes, encourages or suggests to manufacture (defined by statute to include import) the PMN substance of the existence of the SNUR.

(5) Subparagraph (a)(3) shall not negate the effects of any fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2).

(b) Contract Manufacturer. Not withstanding paragraph (a), the Company may cause the Contract Manufacturer(s) identified in the PMN and listed in the Preamble of this Order to manufacture (defined by statute to include import) the PMN substance according to the following

conditions (the Company may petition EPA pursuant to Section VI of this Order to include additional Contract Manufacturers):

(1) The Contact Manufacturer must be under contract to the Company to manufacture (defined by statute to include import) the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for the Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture (defined by statute to include import).

(3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with the conditions specified in the Consent Order for Contract Manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of

assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture (defined by statute to include import) the PMN substance only upon written notification from the Agency.

USE

(a) The Contract Manufacturer shall not use the PMN substance other than as an intermediate.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Contract Manufacturer shall notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN

substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

substance

(b) Distribution Requirements. Except after the PMN has been completely reacted, incorporated into a polymer matrix, or as provided in paragraph (c), the Contract Manufacturer shall distribute the PMN substance outside the Contract Manufacturer, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or incorporated into a polymer matrix. A Contract Manufacturer identified in a fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2) of the Manufacturing section of this Order may further distribute the PMN substance(s) to the Company.

(3) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Protection in the Workplace section of this Order.

(4) Comply with the same requirements and restrictions, if any, required of the Contract Manufacturer in the Hazard Communication Program section of this Order.

(5) Comply with the same environmental release restrictions, if any, required of the

Release to Water section of this Order.

(6) Not use the PMN substance other than as an intermediate.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Contract Manufacturer may distribute the PMN substance outside the Contract Manufacturer for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Contract Manufacturer or a person who has given the Contract Manufacturer the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Contract Manufacturer or a person who has given the Contract Manufacturer the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Contract Manufacturer obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the substance to that recipient, unless the Contract Manufacturer is able to document each of the

following:

(1) That the Contract Manufacturer has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Contract Manufacturer received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Contract Manufacturer obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Contract Manufacturer shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Subparagraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final rule modifying the SNUR at 40 CFR 721.5740 to be consistent with the conditions set forth in this order, unless the Contract Manufacturer is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Contract Manufacturer is so notified, subparagraph (b)(2) of this Distribution section shall not expire until

EPA notifies the Contract Manufacturer in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final modified SNUR for the PMN substance and subparagraph (b)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Contract Manufacturer shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Contract Manufacturer provides such notice to the persons to whom it distributes the PMN substance, then the Contract Manufacturer is not required to obtain from such persons the written agreement specified in paragraph (b).

RELEASE TO WATER

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Contract Manufacturer is prohibited from any predictable or purposeful release of the PMN substance, or any waste stream from manufacturing/processing/use containing the PMN substance into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds 6 parts per billion, when calculated using the methods described in 40 CFR 721.91. However, 40 CFR 721.91(a)(4) does not apply. Instead, if control technologies are in place to treat the waste stream containing the PMN substance, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 40 percent removal efficiency may be attributed to such treatment.

In lieu of calculating the quotient, monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Contract Manufacturer of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

III. RECORDKEEPING

(a) Records. The Contract Manufacturer shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Contract Manufacturer. Any amounts or batches of the PMN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Contract Manufacturer maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Contract Manufacturer shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (defined by statute to include import) volume of the PMN substance and the corresponding dates of manufacture (defined by statute to include import);

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (defined by statute to include import) to whom the Contract Manufacturer directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (defined by statute to include import), processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(7) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(8) Copies of labels required under the Hazard Communication Program section of this Order;

(9) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(10) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(11) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(12) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(13) The Contract Manufacturer shall keep a copy of this Order at each of its sites where the PMN substance is manufactured (defined by statute to include import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Contract Manufacturer facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Contract Manufacturer in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;.

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Contract Manufacturer's Response. The Contract Manufacturer shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Contract Manufacturer's response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Contract Manufacturer at the time of the request, the Contract Manufacturer's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Contract Manufacturer submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Contract Manufacturer may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. .The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Contract Manufacturer may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Contract Manufacturer waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Contract Manufacturer as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Contract Manufacturer may have under TSCA.

(b) CBI Brackets. By signing this Order, the Contract Manufacturer represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Contract Manufacturer (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

10/29/14
Date

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

[redacted]